This form will help you determine whether clinical research billing review is required for your eResearch submission to ensure consistency with the Medicare Clinical Research Policy.

**Question in eResearch (eRRM), 14-1.1**

Does your study have any items, services, tests or procedures that are performed as part of the research protocol and will be **billed** to, or paid for by any of the following (this includes study specific and/or routine care items).

**Choose all that apply:**
- A health plan
- External Sponsor (External to UMHS)
- Internal Award (Internal to UMHS)
- Subject or legal guardian
- Research Medical Record Number (RMRN)
- None of the above (see 14-1.2 below)

*Note*

Billable items, services, tests or procedures include routine care items, services, tests or procedures that are billed to either the patient or a health plan, or research specific items, services, tests or procedures billed to a research study account. If any type of charge is generated for the item, service, test or procedure that is sent to the subject, health plan or research sponsor, you must complete a billing calendar. [A research sponsor includes both internal and external awards.] For questions or concerns, please contact the CRAO at 998-6880 or CR2-AO@med.umich.edu.

**14-1.2** If you selected “None of the above” in section 14-1.1, check at least one of the following describing this activity.

**Activity and Description:**
- Retrospective or Prospective Chart Review (Review of health outcomes from medical chart)
- Specimens used in research (Obtained by/released to study team members for non-therapeutic analyses with no lab or specimen processing charges.)
- Questionnaire/Survey (The only component of research for your study is the completion of questionnaires or surveys)
- Research Only Space and research staff used (All the items/services take place in a physical space designated for research including all costs associated with the space and/or the analysis,

Approved: 3.14.13
Revised: 3.14.13
Calendar Review Analysis Office
Exemption Determination Form
Interpretation, and/or report of a lab or X-ray results are performed by the PI. There would be no charge(s) created and billed via the MiChart billing system.

Other: Please explain the specific circumstances of your research that prevents items/services from being generated.

14-1.3 If you indicated in section 14-1.1 that your study has items, services, test or procedures that will be billed to one or more of the listed options, please complete a billing calendar. For questions or concerns, please contact the CRAO at 998-6880 or CR2-AO@med.umich.edu.

If you answered YES to any of the four questions in section 14-1.1:

Your research must undergo a clinical research billing review and approval prior to IRB approval. For this review, a billing calendar categorizing which services are billed to research, other University accounts, insurance and/or patients is required. The billing calendar must be generated within Michigan Budget Enrollment Calendar Tool (MBECT). If you need MBECT assistance, email CRAO-MBECT-help@med.umich.edu or call 764-KNOW (5669).

In order for CRAO to properly complete the Medicare Coverage Analysis (MCA) and clinical research billing review, the study team must submit, in eResearch (eRRM or eRPM), the following documents:

- Protocol
- Informed Consent
- Billing Calendar (MBECT format)
- Budget(s) (if applicable)
- Grant(s)/Contract(s) (if applicable; Draft versions are acceptable)

All documents can be either the working documents (that you believe are final), or to expedite review, draft versions. Upon receipt of the protocol, consent, sponsor budget information, and billing calendar, we will begin the review process. The CRAO will compare all documents to check for congruency. If there are any questions, the Analyst assigned to the study will be in contact with the study team for clarification. Once all documents are aligned and the billing calendar has been considered final, CRAO will return the application to the study team for final PI approval of the calendar which should then be uploaded into eResearch, section 14-1.3. The CRAO will then approve the application by attaching the approval letter and MCA in eResearch Regulatory Management.

The final “Approved” billing calendar for the study will be used to confirm that charges for enrolled study subjects are handled appropriately. The information from the billing calendar is passed onto
MiChart to allow for recognition of the allowable procedures for your study and to route the charges to either the study account or to the patient/insurance.

All subject enrollment and disenrollment should be reported in MBECT the same day as the Informed Consent is signed and the day the subject is no longer active in your study.

GLOSSARY OF TERMS

**Billable:** Items or services that are processed and charged via a UMHS billing system (MiChart).

**Billing Calendar:** A tool used to determine who is responsible for paying for each item/service provided to research subjects in a clinical trial. A Billing Calendar lists the items/services, number of research visits, and notes which items/services are performed during each research visit. A Billing Calendar categorizes billable events that a subject/patient may encounter/receive during a research visit. A Billing Calendar is not a budget.

**Human Subjects Research:** Federal regulations define a "Human Subject" as: "[A] living individual about whom an investigator conducting research obtains: (1) Data through intervention or interaction with the individual, or (2) Identifiable private information" (45 CFR 46.102[f]). "Research" is defined as: "[A] systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" (45 CFR 46.102[d]).

**Research Medical Record Number (RMRN):** A number that is generated by MiChart and allows patient specific charges to be processed so; they are paid for with research funds. Each study with research specific billable charges should be assigned one RMRN account and this RMRN account should not be used for any other study. Studies prior to MiChart keep their 7000 research account number.

**MCA:** Medicare Coverage Analysis: For detailed information please see the “Clinical Research Billing Guidance” tab on the CRAO website.

OTHER HELPFUL TERMS

**Emergency One-Time Use:** One-time, non-research use of an investigational agent or unapproved device for the treatment of a life threatening condition.

**Humanitarian Use Device:** Non-research use of an HUD device that is intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect or is manifested in fewer than 4,000 individuals in the United States per year.